

Applied Pharmaceutical Analysis

An introductory text, written with the needs of the student in mind, which explains all the most important techniques used in the analysis of pharmaceuticals - a key procedure in ensuring the quality of drugs . The text is enhanced throughout with keypoints and self-assessment boxes, to aid student learning. Features Includes worked calculations to demonstrate mathematics in use for pharmaceutical analysis. Focuses on key points rather than a large number of facts to help readers really understand the field as well as pass exams. Includes self-assessment, focussing on simple arithmetical calculation results from analytical data. Additional section on basic calculations in pharmaceutical analysis More detail on the capillary electrophoresis of proteins A discussion of some of the new types of HPLC column and on solvent selectivity in HPLC Additional material inserted on the control of the quality of analytical methods, mass spectrometry and high pressure liquid chromatography Additional self-assessment exercises

Pharmaceutical Analysis is a compulsory subject offered to all the under graduate students of Pharmacy. This book on Pharmaceutical Analysis has been designed considering the syllabi requirements laid down by AICTE and other premier institutes/universities. The book covers both the Titrimetric and Instrumental aspects of Pharmaceutical analysis which is helpful for use in multiple semesters.

Revision guide for students giving points of basic information on applied pharmacy practice followed by questions and answers.

Practical Pharmaceutical Analytical Techniques book is meant for undergraduate and postgraduate pharmacy and science students. Chemistry is a fascinating branch of science.

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Practical aspects of chemistry are interesting due to colour reactions, synthesis of drugs, analysis and observation of beautiful crystal development. The important aspects involved in the practicals of pharmaceutical analytical chemistry have been comprehensively covered in the book. I hope the students studying practical aspects of pharmaceutical analysis would be benefitted from this book. In the book, different pharmaceutical analytical techniques (PAT) have discussed with their applications followed by general and specific safety notes in detail. Explanation of some common laboratory processes are given followed by a number of equipments, apparatuses and glass wares used in a pharmaceutical analytical chemistry lab. Limit tests with explanation have been given. Basic concepts related to spectroscopic and chromatographic techniques are discussed. Procedure to calibrate a UV spectrometer is provided with concept. Preparation of calibration curve followed by assay method for analysis of ciprofloxacin, metformin, and rifampicin are explained. Interpretation of IR spectra of ethanol, acetone, formaldehyde and aspirin has been explained in simple language. The working of HPLC instrument is given with its parts. Paracetamol's assay by HPLC is discussed. TLC experiments of amino acid, food dye pigments, and an OTC drug are also furnished. Preparation of commonly used reagents has also been given.

This book explains task management concepts and outlines practical knowledge to help pharmaceutical analytical scientists become productive and enhance their career. •Presents broad topics such as product development process, regulatory requirement, task and project management, innovation mindset, molecular recognition, separation science, degradation chemistry, and statistics. •Provokes thinking through figures, tables, and case studies to help understand how the various functions integrate and how analytical development can work

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efficiently and effectively by applying science and creativity in their work. •Discusses how to efficiently develop a fit-for-purpose HPLC method without screening dozens of columns, gradients, or mobile phase combinations each time, since the extra effort may not provide enough of a benefit to justify the cost and time in a fast-paced product development environment. This book explains task management concepts and outlines practical knowledge to help pharmaceutical analytical scientists become productive and enhance their career. •Presents broad topics such as product development process, regulatory requirement, task and project management, innovation mindset, molecular recognition, separation science, degradation chemistry, and statistics. •Provokes thinking through figures, tables, and case studies to help understand how the various functions integrate and how analytical development can work efficiently and effectively by applying science and creativity in their work. •Discusses how to efficiently develop a fit-for-purpose HPLC method without screening dozens of columns, gradients, or mobile phase combinations each time, since the extra effort may not provide enough of a benefit to justify the cost and time in a fast-paced product development environment.

The definitive textbook on the chemical analysis of pharmaceutical drugs – fully revised and updated Introduction to Pharmaceutical Analytical Chemistry enables students to gain fundamental knowledge of the vital concepts, techniques and applications of the chemical analysis of pharmaceutical ingredients, final pharmaceutical products and drug substances in biological fluids. A unique emphasis on pharmaceutical laboratory practices, such as sample preparation and separation techniques, provides an efficient and practical educational framework for undergraduate studies in areas such as pharmaceutical sciences, analytical

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chemistry and forensic analysis. Suitable for foundational courses, this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals. This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals, which includes discussions on identification, purity testing and assay of peptide and protein-based formulations. Also new to this edition are improved colour illustrations and tables, a streamlined chapter structure and text revised for increased clarity and comprehension. Introduces the fundamental concepts of pharmaceutical analytical chemistry and statistics Presents a systematic investigation of pharmaceutical applications absent from other textbooks on the subject Examines various analytical techniques commonly used in pharmaceutical laboratories Provides practice problems, up-to-date practical examples and detailed illustrations Includes updated content aligned with the current European and United States Pharmacopeia regulations and guidelines Covering the analytical techniques and concepts necessary for pharmaceutical analytical chemistry, Introduction to Pharmaceutical Analytical Chemistry is ideally suited for students of chemical and pharmaceutical sciences as well as analytical chemists transitioning into the field of pharmaceutical analytical chemistry. This book describes the role modern pharmaceutical analysis plays in the development of new drugs. Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug. Coverage includes state-of-the-art topics such as analytics for combinatorial chemistry and high-throughput screening, formulation development, stability studies, international regulatory aspects and documentation, and future technologies that are likely to impact the field. Emphasis is placed on current, easy-to-follow

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methods that readers can apply in their laboratories. No book has effectively replaced the very popular text, *Pharmaceutical Analysis*, that was edited in the 1960s by Tak Higuchi. This book will fill that gap with an up-to-date treatment that is both handy and authoritative.

This introductory text highlights the most important aspects of a wide range of techniques used in the control of the quality of pharmaceuticals. Written with the needs of the student in mind, this clear, practical guide includes self-testing sections with arithmetical examples and tests to help students brush up on their arithmetical skills in an applied context. Covers all of the most important analysis techniques in one book. Concentrates on the most important points with just the right level of detail. Summarizes the relevant theory but avoids becoming too esoteric. Features chapter summaries, key points and self-assessment boxes. Includes arithmetical calculations of results in the self-assessment exercises. Additional section on basic calculations in pharmaceutical analysis More detail on the capillary electrophoresis of proteins A discussion of some of the new types of HPLC column and on solvent selectivity in HPLC Additional material inserted on the control of the quality of analytical methods, mass spectrometry and high pressure liquid chromatography Additional self-assessment exercises The editors have engaged leading scientists in the field to participate in the development of this book, which is envisioned as a “one of a kind” contribution

to the field. The book is a comprehensive text that puts fundamental bioanalytical science in context with current practice, its challenges and ongoing developments. It expands on existing texts on the subject by covering regulated bioanalysis of both small and large molecule therapeutics from both a scientific and regulatory viewpoint. The content will be useful to a wide spectrum of readers: from those new to bioanalysis; to those developing their experience in the laboratory, or working in one of the many critical supporting roles; to seasoned practitioners looking for a solid source of information on this exciting and important discipline.

This book provides a comprehensive guide on validating analytical methods. Key features: Full review of the available regulatory guidelines on validation and in particular, ICH. Sections of the guideline, Q2(R1), have been reproduced in this book with the kind permission of the ICH Secretariat; Thorough discussion of each of the validation characteristics (Specificity; Linearity; Range; Accuracy; Precision; Detection Limit; Quantitation Limit; Robustness; System Suitability) plus practical tips on how they may be studied; What to include in a validation protocol with advice on the experimental procedure to follow and selection of appropriate acceptance criteria; How to interpret and calculate the results of a validation study including the use of suitable statistical calculations; A fully

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explained case study demonstrating how to plan a validation study, what to include in the protocol, experiments to perform, setting acceptance criteria, interpretation of the results and reporting the study.

The use of analytical sciences in the discovery, development and manufacture of pharmaceuticals is wide-ranging. From the analysis of minute amounts of complex biological materials to the quality control of the final dosage form, the use of analytical technology covers an immense range of techniques and disciplines. This book concentrates on the analytical aspects of drug development and manufacture, focusing on the analysis of the active ingredient or drug substance. It provides those joining the industry or other areas of pharmaceutical research with a source of reference to a broad range of techniques and their applications, allowing them to choose the most appropriate analytical technique for a particular purpose. The volume is directed at analytical chemists, industrial pharmacists, organic chemists, pharmaceutical chemists and biochemists.

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pharmaceutical products and drug substances in biological fluids. A unique emphasis on pharmaceutical laboratory practices, such as sample preparation and separation techniques, provides an efficient and practical educational framework for undergraduate studies in areas such as pharmaceutical sciences, analytical chemistry and forensic analysis. Suitable for foundational courses, this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals. This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals, which includes discussions on identification, purity testing and assay of peptide and protein-based formulations. Also new to this edition are improved colour illustrations and tables, a streamlined chapter structure and text revised for increased clarity and comprehension. Introduces the fundamental concepts of pharmaceutical analytical chemistry and statistics Presents a systematic investigation of pharmaceutical applications absent from other textbooks on the subject Examines various analytical techniques commonly used in pharmaceutical laboratories Provides practice problems, up-to-date practical examples and detailed illustrations Includes updated content aligned with the current European and United States Pharmacopeia regulations and guidelines Covering the analytical techniques and concepts necessary for pharmaceutical

analytical chemistry, Introduction to Pharmaceutical Analytical Chemistry is ideally suited for students of chemical and pharmaceutical sciences as well as analytical chemists transitioning into the field of pharmaceutical analytical chemistry.

This book provides a broad account of various applied aspects of microbiology for quality and safety evaluations in food, water, soil, environment and pharmaceutical sciences. The work is timely, as the safety and quality of various commodities such as water and wastewater, food, pharmaceutical medications and medical devices are of paramount concern in developing countries globally for improved public health quality in areas ranging from food security to disease exposure. The book offers an introduction to basic concepts of biosafety and related microbiological practices and applies these methodologies to a multitude of disciplines in subject-focused chapters. Each chapter offers experiments and exercises pertaining to the specific area of interest in microbiological research, which will allow readers to apply the knowledge gained in a laboratory or classroom setting to see the microbiological methods discussed in practice. The book will be useful for industrialists, researchers, academics and undergraduate/graduate students of microbiology, biotechnology, botany and pharmaceutical sciences. The text aims to be a significant contribution in

effectively guiding scientists, analysts, lab technicians and quality managers working with microbiology in industrial and commercial fields.

Consolidates the information LC-MS bioanalytical scientists need to analyze small molecules and macromolecules The field of bioanalysis has advanced rapidly, propelled by new approaches for developing bioanalytical methods, new liquid chromatographic (LC) techniques, and new mass spectrometric (MS) instruments. Moreover, there are a host of guidelines and regulations designed to ensure the quality of bioanalytical results. Presenting the best practices, experimental protocols, and the latest understanding of regulations, this book offers a comprehensive review of LC-MS bioanalysis of small molecules and macromolecules. It not only addresses the needs of bioanalytical scientists working on routine projects, but also explores advanced and emerging technologies such as high-resolution mass spectrometry and dried blood spot microsampling. Handbook of LC-MS Bioanalysis features contributions from an international team of leading bioanalytical scientists. Their contributions reflect a review of the latest findings, practices, and regulations as well as their own firsthand analytical laboratory experience. The book thoroughly examines: Fundamentals of LC-MS bioanalysis in drug discovery, drug development, and therapeutic drug monitoring The current understanding of regulations governing

LC-MSbioanalysis Best practices and detailed technical instructions for LC-MSbioanalysis method development, validation, and stabilityassessment of analyte(s) of interest Experimental guidelines and protocols for quantitative LC-MSbioanalysis of challenging molecules, including pro-drugs, acylglucuronides, N-oxides, reactive compounds, and photosensitive andautooxidative compounds With its focus on current bioanalytical practice, Handbook ofLC-MS Bioanalysis enables bioanalytical scientists to developand validate robust LC-MS assay methods, all in compliance withcurrent regulations and standards.

This volume on applied pharmaceutical science and microbiology looks at the latest research on the applications of natural products for drug uses. It focuses on understanding how to apply the principles of novel green chemistry methods in the vital area of pharmaceuticals and covers the important aspects of green microbial technology in the pharmaceutical industry. Chapters include studies on the applications of natural products used in folk and regional medicines, such as for digestive problems, dermatological infections, respiratory diseases, vessel diseases, diarrhea and dysentery, ringworms, boils, fevers (antipyretic), skin and blood diseases, mouth sores, channel discharges, and even cancer. The volume also looks at medical benefit of microbial fermentation for the conservation of nutrients.

Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2012 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Chromatography. The editors have built Issues in Analysis,

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Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2012 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Chromatography in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2012 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at <http://www.ScholarlyEditions.com/>.

Filling a gap in the literature for a hands-on guide focusing on everyday laboratory challenges, this English edition has been expanded and revised using the feedback received on the successful German precursor. Throughout the book, Professor Mascher draws on his 30 years of experience and provides abundant practical advice, troubleshooting and other hints highlighted in boxes, as well as a broad selection of walkthrough case studies. Based on a course taught by the author, the first part of the book intuitively explains all steps of routine bioanalysis and explains how to set up a robust, inexpensive and efficient method for a given substance. In the second part he includes 20 worked example cases that highlight common challenges and how to overcome them. With its appendix containing tried-and-tested analytical methods for 100 clinically relevant substances from the author's own laboratory, complete with spectral and MS data as well as literature references and basic pharmacokinetic information, this is a life-long companion for everyone working in clinical, pharmaceutical and biochemical

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analysis. Comments to the German book: "The book comes to life through its examples, showing not only what did work in the author's laboratory, but also what didn't." ChemieReport "Indispensable for novices, while even old hands will be able to expand their knowledge. A collection of analytical data for ca. 100 substances completes the book's offering, leaving almost nothing to be desired." pharmind

Recent advances in the pharmaceutical sciences and biotechnology have facilitated the production, design, formulation and use of various types of pharmaceuticals and biopharmaceuticals. This book provides detailed information on the background, basic principles, and components of techniques used for the analysis of pharmaceuticals and biopharmaceuticals. Focusing on those analytical techniques that are most frequently used for pharmaceuticals, it classifies them into three major sections and 19 chapters, each of which discusses a respective technique in detail. Chiefly intended for graduate students in the pharmaceutical sciences, the book will familiarize them with the components, working principles and practical applications of these indispensable analytical techniques.

Vibrational Spectroscopy Applications in Biomedical, Pharmaceutical and Food Sciences synthesizes the latest research on the applications of vibrational spectroscopy in biomedical, pharmaceutical and food analysis. Suitable for graduate-level students as well as experienced researchers in academia and industry, this book is organized into five distinct sections. The first deals with the fundamentals of vibrational spectroscopy, with the second presenting the most important sampling methodology used for infrared and Raman spectroscopy in various fields of interest. Since spectroscopy is the study of the interaction of electromagnetic radiation with matter, this section deals with the characteristics, properties and absorption of

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electromagnetic radiation. Final sections describe the analytical studies performed all over the world in biomedical, pharmaceutical and in the food sciences. Presents a critical discussion of many of the applications of vibrational spectroscopy Covers details of the analytical methodologies used in pharmaceutical and biomedical applications Discusses the latest developments in pharmaceutical and biomedical analysis of both small and large molecules Pharmaceutical analysis determines the purity, concentration, active compounds, shelf life, rate of absorption in the body, identity, stability, rate of release etc. of a drug. Testing a pharmaceutical product involves a variety of chemical, physical and microbiological analyses. It is reckoned that over £10 billion is spent annually in the UK alone on pharmaceutical analysis, and the analytical processes described in this book are used in industries as diverse as food, beverages, cosmetics, detergents, metals, paints, water, agrochemicals, biotechnological products and pharmaceuticals. This is the key textbook in pharmaceutical analysis, now revised and updated for its fourth edition. Worked calculation examples Self-assessment Additional problems (self tests) Practical boxes Key points boxes New chapter on Biotech products. New chapter on electrochemical methods in diagnostics. Greatly extended chapter on molecular emission spectroscopy to accommodate developments and innovations in the area. Now on StudentConsult

For almost a decade, quantitative NMR spectroscopy (qNMR) has been established as valuable tool in drug analysis. In all disciplines, i. e. drug identification, impurity profiling and assay, qNMR can be utilized. Separation techniques such as high performance liquid chromatography, gas chromatography, super fluid chromatography and capillary electrophoresis techniques, govern the purity evaluation of drugs. However, these techniques

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are not always able to solve the analytical problems often resulting in insufficient methods. Nevertheless such methods find their way into international pharmacopoeias. Thus, the aim of the book is to describe the possibilities of qNMR in pharmaceutical analysis. Beside the introduction to the physical fundamentals and techniques the principles of the application in drug analysis are described: quality evaluation of drugs, polymer characterization, natural products and corresponding reference compounds, metabolism, and solid phase NMR spectroscopy for the characterization drug substances, e.g. the water content, polymorphism, and drug formulations, e.g. tablets, powders. This part is accompanied by more special chapters dealing with representative examples. They give more detailed information by means of concrete examples. Combines theory, techniques, and concrete applications—all of which closely resemble the laboratory experience Considers international pharmacopoeias, addressing the concern for licensing Features the work of academics and researchers, appealing to a broad readership

This second edition of a global best-seller has been completely redesigned and extensively rewritten to take into account the new Quality by Design (QbD) concept in pharmaceutical manufacturing. As in the first edition, the analytical requirements during the entire product lifecycle are covered, but now a new section is included on continued performance monitoring and the transfer of analytical procedures. Two case studies from the pharmaceutical industry illustrate the concepts and guidelines presented, and the standards and regulations from the US (FDA), European (EMA) and global (ICH) regulatory authorities are considered throughout. The undisputed gold standard in the field.

Proceedings of the Conference on Applied Physical Chemistry Incöuding Pharmaceutical

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Analysis. Instrumental analysis Pharmaceutical Analysis John Wiley & Sons

If you are new to HPLC, this book provides an invaluable guide to how HPLC is actually used when analysing pharmaceuticals. It is full of practical advice on the operation of HPLC systems combined with the necessary theoretical knowledge to ensure understanding of the technique. Key features include: A thorough discussion of the stationary phase enabling the reader to make sense of the many parameters used to describe a HPLC column; Practical advice and helpful hints for the preparation and use of mobile phase; A complete overview of each of the different components which together make up a HPLC system; A description of the contents of a typical HPLC analytical method and how to interpret these; A step-by-step guide on how to follow a method and set up a HPLC analysis; A discussion of system suitability criteria and how to interpret the values obtained during an analysis; Explanation of the common methods of calibration and quantification used for pharmaceutical analysis.

Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists highlights the most important aspects of a wide range of techniques used in the control of the quality of pharmaceuticals, including spectroscopy, chromatography, and electrophoresis. This clear, practical guide also includes self-testing sections and arithmetical examples and tests to help students brush up on their arithmetical skills in an applied context.

This book covers the most recent research trends and applications of Pharmaceutical Analytical Chemistry. The included topics range from the adulteration of dietary supplements, to the determination of drugs in biological samples with the aim to investigate their pharmacokinetic properties.

This book provides a serious introduction to the subject of mass spectrometry, providing the

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reader with the tools and information to be well prepared to perform such demanding work in a real-life laboratory. This essential tool bridges several subjects and many disciplines including pharmaceutical, environmental and biomedical analysis that are utilizing mass spectrometry: Covers all aspects of the use of mass spectrometry for quantitation purposes Written in textbook style to facilitate understanding of this topic Presents fundamentals and real-world examples in a 'learning-thought-doing' style

This textbook is the first to present a systematic introduction to chemical analysis of pharmaceutical raw materials, finished pharmaceutical products, and of drugs in biological fluids, which are carried out in pharmaceutical laboratories worldwide. In addition, this textbook teaches the fundamentals of all the major analytical techniques used in the pharmaceutical laboratory, and teaches the international pharmacopoeias and guidelines of importance for the field. It is primarily intended for the pharmacy student, to teach the requirements in "analytical chemistry" for the 5 years pharmacy curriculum, but the textbook is also intended for analytical chemists moving into the field of pharmaceutical analysis. Addresses the basic concepts, then establishes the foundations for the common analytical methods that are currently used in the quantitative and qualitative chemical analysis of pharmaceutical drugs Provides an understanding of common analytical techniques used in all areas of pharmaceutical development Suitable for a foundation course in chemical and pharmaceutical sciences Aimed at undergraduate students of degrees in Pharmaceutical Science/Chemistry Analytical Science/Chemistry, Forensic analysis Includes many illustrative examples

New Developments for Nanosensors in Pharmaceutical Analysis presents an

overview of developments in nanosensor usage in pharmaceutical analysis, thereby helping pharmaceutical companies attain reliable, precise, and accurate analysis of pharmaceuticals. This book presents very simple, precise, sensitive, selective, fast, and relatively inexpensive methods for pre-treatment, prior to analysis. These methods may be considered for further application in clinical studies and assays. The book includes the manufacturing of sensors for pharmaceutical analysis at nano- or smaller scales, and gives simple and relatable designs for the fabrication of sensors. Twelve chapters cover an introduction to the topic, immobilization techniques, mechanism effect of nanomaterials on structure, optical nanosensors for pharmaceutical detection, chemical nanosensors in pharmaceutical analysis, noble metal nanoparticles in electrochemical analysis of drugs, photo-electrochemical nanosensors for drug analysis, molecularly imprinted polymer based nanosensors for pharmaceutical analysis, nanomaterials for drug delivery systems, nanomaterials enriched nucleic acid-based biosensors, nanosensors in biomarker detection, and nanomaterials-based enzyme biosensors for electrochemical applications. Presents nanosensor types, synthesis, immobilizations and applications in different fields Gives simple repeatable designs for the fabrication of sensors for pharmaceutical analysis Details how to carry out sensitive analysis of

pharmaceuticals using nanosensors Describes how to synthesize and immobilize nanosensors, and how nanosensors can be applied in drug assay Proposes innovative ways to optimize pharmaceutical processes with nanosensors Exploring the analysis of pharmaceuticals, including polymorphic forms, this book discusses regulatory requirements in pharmaceutical product development and pharmaceutical testing. It covers methods of drug separation and procedures such as capillary electrophoresis for chromatographic separation of molecules. Additional topics include drug formulation analysis using vibrational and magnetic resonance spectroscopy and identification of drug metabolites and decomposition products using such techniques as mass spectrometry. The book provides more than 300 tables, equations, drawings, and photographs, and convenient, easy-to-use indices, facilitating quick access to each topic. Capillary electrophoresis (CE) is a powerful analytical technique that is widely used in research and development and in quality control of pharmaceuticals. Many reports of highly efficient separations and methods have been published over the past 15 years. CE offers several advantages over high-pressure or high-performance liquid chromatography (HPLC). These include simplicity, rapid analysis, automation, ruggedness, different mechanisms for selectivity, and low cost. Moreover, EC requires smaller sample size and yet offers higher efficiency

and thus greater resolution power over HPLC. These characteristics are very attractive in research and development, even more so in pharmaceutical quality control (QC) and stability monitoring (SM) studies. This book will provide busy pharmaceutical scientists a complete yet concise reference guide for utilizing the versatility of CE in new drug development and quality control. - Provides current status and future developments in CE analysis of pharmaceuticals. - Explains how to develop and validate methods. - Includes major pharmaceutical applications including assays and impurity testing.

A single-source reference with a broad and holistic overview of nonclinical studies, this book offers critical training material and describes regulations of nonclinical testing through guidelines, models, case studies, practical examples, and worldwide perspectives. The book: Provides a complete overview of nonclinical study organization, conduct, and reporting and describes the roles and responsibilities of a Study Director to manage an effective study Covers regulatory and scientific concepts, including international testing and Good Laboratory Practice (GLP), compliance with guidelines, and animal models Features a concluding chapter that compiles case studies / lessons learned from those that have served as a Study Director for many years Addresses the entire spectrum of nonclinical testing, making it applicable to those in the government,

laboratories and those actively involved in in all sectors of industry
Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmacutists, QA officers, and public authorities.

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